

## **”Risk based” prioritisation in REACH**

### ***The starting point***

The most important factor that triggered the White paper and the REACH proposal is the realisation that the knowledge about properties/risks with existing chemicals is wholly inadequate, and that the available risk based instrument to generate new knowledge (the existing substances program) did not work. One substantial problem that was recognised is that knowledge is lacking even of fundamental inherent properties of chemicals, i.e. whether they have a potential to create risks in actual use.

A major new idea with REACH is therefore that all chemicals should have a basic set of data about their inherent properties, which can be used to assess risks. Industry shall provide the data and assess the risks as part of registration.

What data is required depends on tonnages produced/imported (one way of prioritising), but the view of Sweden and many others is that the information should at least be enough to classify a substance in danger categories. The Commission’s proposal does not live up to this requirement as regards the lowest tonnage bracket (1-10 tonnes), which could represent two thirds of the 30 000 existing chemicals subject to registration.

### ***Discussions in Council***

Discussions in the ad hoc working group have mostly been about the requirements for the 1-10 tonne range. The data requirements for higher levels in the Commission’s proposal have generally not been questioned. Some delegations, including Sweden, have asked for stricter requirements for this range, while others want to stick to the Commission proposal. Malta and Slovenia have suggested another approach for 1-10 tonne range, which is based on available information in combination with a risk assessment. This assessment can in its turn lead to that a need for more data is recognised. This proposal has not been discussed in detail in Council. It has similarities with the CEFIC approach.

### ***The CEFIC proposal***

CEFIC has put forward a proposal for “risk based prioritisation” which is fundamentally different from the approach described above. It would in fact mean going back to the approach in the existing substances program, which REACH was supposed to replace. The CEFIC proposal is described in the attached short paper. It has also been criticized in a paper from the German Environment Ministry which is available in English.

The CEFIC ideas have not been taken up by the rapporteurs in Parliament who have proposed amendments so far (Sacconi, Ek, Hassi) and has not been supported by the Commission.

## ***Conclusions***

- The CEFIC approach would be contrary to one of the main purposes of REACH – dealing with the lack of knowledge that has been described as the ‘burden of the past’ in chemicals management.
- Any discussion on changes in the approach for registration should be limited to the low volume chemicals (1-10 tonnes), where it is recognised that the present proposal is inadequate. The CEFIC proposal is not enough to deal with the problems for this range.

## **Preliminary comments on industry's proposals for prioritisation of substances based on risk**

By documents dated 24 Feb. and 1 March 2005 Cefic has released a review of the REACH-proposal. Cefic proposes several amendments that they consider to be of high priority. Within the area of Title II –Registration, such high priority proposals are launched for:

- (1) a single time-point for pre-registration of all substances,
- (2) a modified time schedule for the registration of phase-in substances based on annually produced/imported volumes combined with a scoring/prioritisation system alleged to allow the selection of substances posing a “potential high risk”, and
- (3) the abandonment of the tonnage tiered standard information requirements in Annexes V-VIII in favour of a minimal *information set* common to all substances registered in volumes over 10 tonnes per year and *appropriate available information* in the 1-10 tonne volume band. Additional testing is only to be proposed by the registrant when warranted by a potential-high-risk outcome of the scoring/prioritisation system.

### ***A single time-point for pre-registration of all substances***

Cefic proposes a one-step pre-registration process to be completed within 18 months. By this amendment the possibilities of data sharing between registrants would be facilitated and some of the problems with two-step pre-registration process in the REACH-proposal would be avoided. This proposal is therefore supported by Sweden.

### ***A modified time schedule for the registration of phase-in substances***

Under Cefic's alternative plan, manufacturers and importers would have five years to compile at least a minimal information set (>10 tonnes) or appropriate available information (1-10 tonne band). These data together with basic data on use(s) and exposure(s) would be used with “certain electronic support tools” to determine whether or not individual substance poses a "potential high risk" thus allowing prioritisation of substances for an early registration preceding the default tonnage tiered registration deadlines.

Cefic does not specify the “electronic support tools” to be used in the selection of substances posing a "potential high risk". However, it can be anticipated that the

methodology alluded to is the one suggested by the chemical industry's scientific forum ECETOC in their recent publication *Targeted Risk Assessment* (ECETOC Technical Report No. 93, Dec. 2004). This report launches an approach that is not comprehensive and it is far from being scientifically validated. Much work remains before it could be considered for use in a regulatory context. For instance, risks from indirect exposure of humans to chemicals in the environment via e.g. food, water and ambient air are out of the scope of the methodology. Even the publisher, ECETOC, underlines that the risk assessment tools catered for need to be developed further and need to be scrutinised and eventually agreed among the relevant stakeholders.

Cefic's first registration deadline at REACH+5 years (5 years after REACH enters into force) would cover substances manufactured/imported at >1000 tonnes per year and the cat. 1&2 CMRs. At REACH+7 years substances manufactured/imported at 100-1000 tonnes per year and all substances in the 1-100 tonne per year bracket posing a "potential high risk" would be due for registration. Eventually, at REACH+9 years and REACH+11 years, respectively, the remaining substances not posing potential high risk in the two lower tonnage bands would be registered.

Compared to the REACH-proposal, the Cefic plan would lead to a 1-2-year delay in the registration of all substances with volumes over 100 tonne per year and the CMRs. The registration of the potential-high-risk substances in the 1-100 tonne band would be brought forward 2-4 years. For the non-prioritised lower volume substances a 2-year earlier registration deadline is suggested for the 10-100 tonne band, while the substances in the 1-10 tonne band would keep their 11-year deadline from the REACH-proposal.

Thus, a substantial delay in the registration of all higher volume substances is suggested to be traded against the hypothetical possibility of having an uncertain number of lower volume substances prioritised for an earlier registration.

A minimal information set common to all substances over 10 tonnes per year and appropriate available information for low volume substances

The minimum information set suggested to be a common requirement for all registrations of substances in volumes over 10 tonnes per year is substantially reduced as compared to the REACH-proposal for the 10-100 tonne band – e.g. data on repeated dose toxicity, reproductive toxicity and several ecotoxicological end-points are no longer included.

Cefic further proposes that a negative outcome (i.e. no concern) of the proposed screening for substances of "potential high risk" based on the minimum information set would lead to a generic conclusion of "safe use". Then, the information requirements in Annexes VII & VIII comprising the more demanding long-term (eco)toxicity studies would not apply and there would be no need for a substance evaluation. If such "safe use" could not be concluded, the registrant would submit testing proposals to be handled in the dossier evaluation by the Member state CAs and the Agency. Cefic thus seems to claim a carte blanche from information demands additional to the minimum information set once a substance is cleared by the scoring/prioritisation system for the selection of substances posing a "potential high risk". This proposal certainly raises concern due to the premature and sketchy nature of the prioritisation methodology, which isn't even referenced by Cefic.

For the low volume substances Cefic offers even more relaxation regarding the duties of the registrants. Substituting *appropriate available information* for the already inadequate information requirements (Annex V) for the low volume substances (1-10 tonne per year) as suggested by Cefic goes far beyond acceptability. Furthermore, the methodology for risk prioritisation drafted by ECETOC requires a specified minimum information set in order to be applicable.